



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA-2018-N-3772]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Active Implantable Bone Conduction Hearing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the active implantable bone conduction hearing system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the active implantable bone conduction hearing system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The classification was applicable on July 20, 2018.

FOR FURTHER INFORMATION CONTACT: Oldooz Hazrati, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2455, Silver Spring, MD 20993-0002, 240-402-9903, Oldooz.HazratiYadkooori@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the active implantable bone conduction hearing system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first

procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 16, 2017, MED-EL Elektromedizinische Geraete GmbH submitted a request for De Novo classification of the BONEBRIDGE. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 20, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.3340. We have named the generic type of device active implantable bone conduction hearing system, and it is identified as a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Active Implantable Bone Conduction Hearing System Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Dural erosion or compression resulting from failure to confirm adequate thickness and consistency of bone and related anatomy	Labeling
Surgical complications leading to	Clinical performance testing and

<ul style="list-style-type: none"> • Bleeding/hematoma • Seizures • Cerebrospinal fluid (CSF) leak • Implant damage or migration leading to revision/explantation 	Labeling
Device software failure	Software verification, validation, and hazard analysis
Implant failure due to: <ul style="list-style-type: none"> • Fatigue • Damage/breakage • Loss of hermeticity 	Clinical performance testing and Non-clinical performance testing
Device failure to compensate for hearing loss	Clinical performance testing and Non-clinical performance testing
Interference with other devices	Electromagnetic compatibility testing, Wireless coexistence testing, Electrical safety testing, and Labeling
Adverse tissue reaction	Biocompatibility evaluation and Labeling
Infection	Sterilization validation, Shelf life testing, and Labeling

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, active implantable bone conduction hearing systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874--EAR, NOSE, AND THROAT DEVICES

1. The authority citation for part 874 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 874.3340 to subpart D to read as follows:

§ 874.3340 Active implantable bone conduction hearing system.

(a) *Identification.* An active implantable bone conduction hearing system is a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must characterize any adverse events observed during implantation and clinical use, and must also demonstrate that the device performs as intended under anticipated conditions of use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Performance data must validate force output in a clinically relevant model.

(ii) Impact testing in a clinically relevant anatomic model must be performed.

(iii) Mechanical integrity testing must be performed.

(iv) Reliability testing consistent with expected device life must be performed.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Performance data must demonstrate the wireless compatibility, electromagnetic compatibility, and electrical safety of the device.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Labeling must include:

(i) A summary of clinical testing conducted with the device that includes a summary of device-related complications and adverse events;

(ii) Instructions for use;

(iii) A surgical guide for implantation, which includes instructions for imaging to assess bone dimensions;

(iv) A shelf life, for device components provided sterile;

(v) A patient identification card; and

(vi) A patient user manual.

Dated: October 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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